

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the January 2001 list were published in the Federal Register in July 2001.

New Approvals

ANADA Number: 200-302

Pioneer Product: 140-971
Trade Name: Iverhart™ Plus Flavored Chewables
Ingredients: Ivermectin, pyrantel pamoate
Sponsor: Blue Ridge Pharmaceuticals, Inc.
Approval Date: May 30, 2001
Status: Prescription only
Route: Oral
Species: Canine
Drug Form: Tablet
Concentration: There are three tablets sizes: 1) 68 micrograms of ivermectin and 57 milligrams of pyrantel; 2) 136 micrograms of ivermectin and 114 milligrams of pyrantel; 3) 272 micrograms of ivermectin and 227 milligrams of pyrantel.
Indications: For the prevention of canine heartworm (*Dirofilaria immitis*) disease and for the treatment and control of adult *Toxocara canis*, *Toxascaris leonina*, *Ancylostoma caninum*, *Uncinaria stenocephala*, and *Ancylostoma braziliense* in dogs over 6 weeks of age.

21CFR 520.1196

ANADA Number: 200-295

Pioneer Product: 065-440
Trade Name: Pennchlor™ 64
Ingredients: Chlortetracycline hydrochloride
Sponsor: PennField Oil Company
Approval Date: April 27, 2001
Status: Over-the-counter
Route: Oral
Species: Cattle, swine, chickens, turkeys
Drug Form: Powder
Concentration: 102.4 grams per packet
Indications: **Calves (not veal), beef cattle and nonlactating dairy cattle and swine:**
Control of bacterial pneumonia (*Pasteurella* spp., *Hemophilus* spp., *Klebsiella* spp.) and bacterial enteritis (*Escherichia coli*, *Salmonella* spp.)
Turkeys:
Control of complicating bacterial organisms associated with bluecomb (transmissible enteritis or Coronavirus enteritis) susceptible to chlortetracycline. Also for the control of infectious synovitis (*Mycoplasma synoviae*)
Chickens:
Control of chronic respiratory disease (CRD) and air-sac infection (*Mycoplasma gallisepticum*, *Escherichia coli*). Also for the control of mortality due to fowl cholera (*Pasteurella multocida*) in growing chickens.
Tolerance: 21CFR 556.150 Chlortetracycline: The Acceptable Daily Intake (ADI) for total residues of tetracyclines including chlortetracycline is 25 micrograms per kilogram of body weight per day. Tolerances are established for the sum of tetracycline residues in tissues of beef cattle, nonlactating dairy cows, calves, swine, chickens, and turkeys, of 2 parts per million (ppm) in muscle, 6 ppm in liver, and 12 ppm in fat and kidney.
Withdrawal: Cattle, chickens, turkeys – one day
Swine – zero days

21CFR 520.445b

Actions Taken by FDA Center for Veterinary Medicine

NADA Number: 141-189

Trade Name: ProHeart[®] 6 Sustained Release Injectable for Dogs
Ingredients: Moxidectin
Sponsor: Fort Dodge Animal Health, Division of American Home Products
Approval Date: June 6, 2001
Status: Prescription only
Route: Subcutaneous
Species: Dogs (6 months or older)
Drug Form: Powder for reconstitution (suspension)
Concentration: 3.4 milligrams per milliliter of constituted suspension
Indications: For the prevention of heartworm disease caused by *Dirofilaria immitis* and for treatment of existing larval and adult hookworm (*Ancylostoma caninum*) infections.
Patent No.: 4,916,154 Expiration date: April 10, 2007
Exclusivity: 3 years

21CFR 522.1451

Supplemental Approvals

NADA Number: 136-742

This supplemental application provides for establishing a tolerance for residues of clorsulon in the muscle tissue of cattle and the deletion of safe concentrations.

Trade Name: Curatrem[®] Drench
Ingredients: Clorsulon
Sponsor: Merial Ltd.
Approval Date: May 16, 2001
Status: Over-the-counter
Route: Oral
Species: Cattle; beef and dairy not lactating
Drug Form: Liquid (suspension)
Concentration: 8.5%
Indications: For the treatment of immature and adult liver fluke (*Fasciola hepatica*).
Tolerance: 21CFR 556.163 Clorsulon: The tolerance for parent clorsulon is 1 part per million in kidney (target tissue) and 100 parts per billion for muscle. The ADI for residues of clorsulon is 8 micrograms per kilogram of body weight per day.
Withdrawal: 8 days

21CFR 556.163

Actions Taken by FDA Center for Veterinary Medicine

Withdrawals

NADA Number: 095-628

Trade Name: Tylosin Antibiotic Premix
Sponsor: Heinold Feeds, Inc.
Date: July 23, 2001

NADA Number: 127-506

Trade Name: Tylan Sulfa-G Premixes
Sponsor: Heinold Feeds, Inc.
Date: July 23, 2001

Suitability Petition Action

Number: 00P-1486/CP1
Sponsor: Equi Aid Products, Inc.
Petition: Request permission to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, ivermectin (Eqvalan), Merial Ltd., NADA 134-314 by the following characteristics: the generic product will consist of a different dosage form ("chewable") and strength (22.7 mg per "chewable") from the pioneer.
Action: Denied on July 26, 2001

Number: 00P-1594/CP1
Sponsor: Highland VetPharma, LLC
Petition: Request permission to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, ivermectin (Eqvalan®), Merial Ltd., NADA 134-314 by the following characteristics: The generic product will consist of a different dosage form (chewable bolus) from the pioneer.
Action: Denied on July 26, 2001

Number: 00P-1600/CP1
Sponsor: Buford Biomedical, Inc.
Petition: Request permission to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, ivermectin (Eqvalan® Paste), Merial Ltd., NADA 134-314 by the following characteristics: Ivermectin generic is a 6.8% powder formulation to be administered in the feed.
Action: Denied on July 26, 2001